MAY - 9 2001

510 (k) Summary

Trade Name	Andersen® Intestinal Tube, Miller-Abbott type (AN 22)
Manufacturer	Andersen Products, Inc. 3202 Caroline Drive Haw River, NC 27258
Device Generic Name	Gastrointestinal tube
Classification	Gastrointestinal tubes have been classified as Class II. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for gastrointestinal tubes.
Predicate Device	Andersen® Intestinal Tube, Miller-Abbott type (AN 21)
Device Description	Sterile, bilumenal, radio opaque, 8ft., size 16 French, weighted intestinal tube with an externally inflatable latex balloon tip. The tube is marked at 65, 75, 100, 125, 150, 175 and 200 cm from the distal end to aid in positioning the tube during passage. The tip of the tube has 24 round aspirating ports designed to reduce clogging of the aspirating tube by screening particulate matter.
Indications for Use	The Andersen® Intestinal Tube, Miller-Abbott type, is indicated in those situations where the aspiration of fluid and air from the gastrointestinal tract is of therapeutic importance, such as in the temporary management of mechanical obstruction of the small or large bowel.
Safety and Performance	Design verification tests including joint tensile strength testing and balloon inflation/leak testing were performed on the Andersen® Intestinal Tube, Miller-Abbott type. In support of this Special 510(k), Andersen Products, Inc. has provided a declaration of conformity to 21 CFR § 820.30 Design Control requirements.
Conclusion	Based on the indications for use and comparison to its predicate device, the Andersen® Intestinal Tube, Miller-Abbott type, has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2001

Ms. Wendy Hedrick
Director, Quality Assurance/Regulatory Affairs
Andersen Products, Inc.
Health Science Park
3202 Caroline Drive
HAW RIVER NC 27258

Re: K011077
Andersen® Intestinal Tube, Miller-Abbott type
(AN 22)
Dated: April 6, 2001
Received: April 9, 2001
Regulatory Class: II
21 CFR §876.5980/Procode: 78 KNT

Dear Ms. Hedrick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use Statement

510(k) Number K011077

Device Name Andersen® Intestinal Tube, Miller-Abbott type (AN 22)

Indications for Use The Andersen® Intestinal Tube, Miller-Abbott type, is indicated in those situations where the aspiration of fluid and air from the gastrointestinal tract is of therapeutic importance, such as in the temporary management of mechanical obstruction of the small or large bowel.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR § 801. 109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011077